

UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF NEW HAMPSHIRE

Marine Polymer Technologies, Inc.

v.

Civil No. 06-cv-100-JD
Opinion No. 2010 DNH 121

HemCon, Inc.

O R D E R

Marine Polymer Technologies, Inc. accused HemCon, Inc. of infringing United States Patent 6,864,245 ("the '245 patent"), and summary judgment was entered in Marine Polymer's favor on infringement. HemCon asserted that the '245 patent was invalid due to anticipation and obviousness.¹ Following trial, the jury returned a verdict that HemCon had not proven anticipation and made factual findings pertaining to obviousness. HemCon now moves for a judgment as a matter of law ("JMOL") that the '245 patent is invalid, due to anticipation and obviousness, and for a new trial. Marine Polymer objects.

¹HemCon also raised other invalidity issues that are not the subject of this order.

Standard of Review

For procedural issues that are not unique to patent law, the Federal Circuit applies the law of the applicable regional circuit. i4i Ltd. P'ship v. Microsoft Corp., 598 F.3d 831, 841 (Fed. Cir. 2010). Motions for a JMOL and for a new trial are governed by the standard applied by the regional circuit. Id.; Lucent Techs., Inc. v. Gateway, Inc., 580 F.3d 1301, 1309 (Fed. Cir. 2009). Therefore, the law of the First Circuit pertaining to motions for a JMOL and for a new trial governs here.

When the court denies a JMOL made after the close of the evidence, the moving party may renew the motion after the jury's verdict and may also request a new trial. Fed. R. Civ. P. 50(b). In considering a post-verdict motion for a JMOL and for a new trial, the court views the evidence in the light most favorable to the nonmoving party. Costa-Urena v. Segarra, 590 F.3d 18, 26 (1st Cir. 2009). "Under Rule 50, the standard for a trial judge to grant a JMOL is whether the jury 'would not have a legally sufficient evidentiary basis' for its verdict." Jennings v. Jones, 587 F.3d 430, 436 (1st Cir. 2009) (quoting Rule 50(a)). "[A] jury's verdict must be upheld unless the facts and inferences, viewed in the light most favorable to the verdict, point so strongly and overwhelmingly in favor of the movant that a reasonable jury could not have returned the verdict." Astro-

Med, Inc. v. Nihon Kohden Am., Inc., 591 F.3d 1, 13 (1st Cir. 2009) (internal quotation marks omitted).

The grounds for granting a new trial are much broader, encompassing any reason that was previously used to grant a new trial. Id. (citing Fed. R. Civ. P. 59(a)(1)(A). One of those grounds is that the verdict is against the weight of the evidence. Jennings, 587 F.3d at 436. In determining whether the verdict is against the weight of the evidence, the court may consider the credibility of the witnesses and weigh the evidence that was presented at trial. Id. The court cannot order a new trial merely because the court disagrees with the jury's verdict. Id.

Discussion

HemCon argues that it is entitled to a JMOL on the invalidity issues of anticipation and obviousness or, alternatively, that the court should order a new trial on those issues. HemCon contends that the evidence at trial made a strong and convincing case of invalidity and that the verdict was against the clear weight of the evidence. Marine Polymer objects to the motion, arguing that the jury properly understood the invalidity issues and came to the right conclusion, based on the evidence at trial.

On summary judgment, the court held that HemCon infringed claims 6, 7, 10, 11, 12, 17, and 20 of the '245 patent. At trial HemCon asserted that claims 6, 7, 10, 11, 12, 17, and 20 were invalid, as anticipated and obvious, based on the following prior art:

1) Paul A. Sandford, "Chitosan: Commercial Uses and Potential Applications, published in Chitin and Chitosan: Sources, Chemistry, Biochemistry, Physical Properties and Applications at pages 51 - 59 (1989);

2) Paul A. Sandford, "Biomedical Applications of New Forms of Chitin/Chitosan" (1992);

3) Protasan Trade Brochure;

4) United States Patent Number 4,394,373 (Malette), and

5) United States Patent Number 3,533,940 (Peniston, et al.).

The jury found that none of the infringed claims were invalid as anticipated and made factual findings pertaining to obviousness.

As HemCon has done in other filings pertaining to invalidity, it again combines arguments and evidence pertaining to anticipation and obviousness for purposes of its motion for judgment as a matter of law or for a new trial. The standard for proving invalidity due to anticipation is different from the standard for proving obviousness. As the court has explained before, HemCon's combined presentation on invalidity confuses the

issues and the pertinent proof, which significantly weakens HemCon's position. The court will address anticipation and obviousness separately.

A. Anticipation

Under 35 U.S.C. § 102, a patent is invalid if its invention was anticipated by prior art, meaning that it was publicly known or used or was previously published under the circumstances described in the statute. Determining whether a patent is invalid due to anticipation presents a factual issue. Orion IP, LLC v. Hyundai Motor Am., --- F.3d ---, 2010 WL 1962037, at *6 (Fed. Cir. May 17, 2010). To prove anticipation, an infringer must show that each and every claim limitation is found either expressly or inherently in a single prior art reference. Yorkey v. Diab, --- F.3d ---, 2010 WL 1337417, at *3 (Fed. Cir. April 7, 2010); Finnigan Corp. v. Int'l Trade Comm'n, 180 F.3d 1354, 1365 (Fed. Cir. 1999).

"A prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." Verizon Servs. Corp. v. Cox Fibernet Va., Inc., 602 F.3d 1325, 1337 (Fed. Cir. 2010) (internal quotation marks omitted). "Inherency, however, may not be established by

probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." Therasense, Inc. v. Becton, Dickinson and Co., 593 F.3d 1325, 1332 (Fed. Cir. 2010) (internal quotation marks omitted). Instead, inherent anticipation requires that the missing element is necessarily present, meaning that "one of ordinary skill in the art would recognize that a reference unavoidably teaches the property in question." Agilent Techs., Inc. v. Affymetrix, Inc., 567 F.3d 1366, 1383 (Fed. Cir. 2009).

To the extent HemCon's anticipation argument in support of its motion for a JMOL or a new trial can be differentiated from its argument on obviousness, HemCon appears to contend that the evidence showed that each element of the infringed claims, claims 6, 7, 10-12, 17, and 20, was disclosed in three prior art references: (1) Paul A. Sandford, "Chitosan: Commercial Uses and Potential Applications, published in Chitin and Chitosan: Sources, Chemistry, Biochemistry, Physical Properties and Applications at pages 51 - 59 (1989) ("1989 Sandford Article"); (2) United States Patent Number 3,533,940 (Peniston, et al.) ("the '940 patent"), and (3) United States Patent Number 4,394,373 (Malette) ("the '373 patent"). Two elements of the claims, biocompatible poly- β -1 \rightarrow 4-N-acetylglucosamine and biocompatible poly- β -1 \rightarrow 4-glucosamine, have been construed to

mean:

polymers with their stated compositions (poly- β -1 \rightarrow 4-N-acetylglucosamine and poly- β -1 \rightarrow 4-glucosamine) and with low variability, high purity, and no detectable biological reactivity as determined by biocompatibility tests.

Marine Polymer contends that HemCon's proof at trial lacked any evidence that the three cited prior art references disclosed biocompatibility as claimed in the '245 patent.

HemCon argues that biocompatibility, as claimed in the '245 patent, was inherently disclosed by the 1989 Sandford Article. In support of that theory, HemCon asserts that the 1989 Sandford Article showed "a sophisticated understanding of quality and biocompatibility," recognized "the desirability for quality control" which would include testing the physical properties of the product, and also recognized "that various degrees of purity or 'biocompatibility' could be achieved depending upon the specific intended medical product application." Def. Mem. dkt. 336-1, at 10. HemCon also asserts that the evidence showed that a person of ordinary skill in the art who wanted to use p-GlcNAc for wound healing would have been motivated by the 1989 Sandford Article "to implement processing to achieve no adverse reactivity." Id. at 11. HemCon concludes that the quality needed for "highest purity" and "for internal body uses . . .

would inherently register as an Elution Test Score of 0 (no reactivity)." Id. at 11-12.

HemCon's argument in support of a JMOL or a new trial on anticipation, based on the 1989 Sanford Article, is not persuasive. As Marine Polymer points out, Dr. Dornish's opinions about the disclosures in the 1989 Sanford Article were based on the wrong definition of biocompatibility. For that reason, Dr. Dornish's opinions do not provide evidence of anticipation.

Based on Dr. Dornish's opinions, HemCon relied on the expected use or application of disclosed p-GlcNAc to show biocompatibility. HemCon contends that the 1989 Sanford Article disclosed that biocompatible p-GlcNAc, meaning p-GlcNAc made with good quality control and high purity, was desirable for particular medical uses. Because of the suggested medical uses, HemCon argues that the 1989 Sanford Article necessarily intended biocompatible p-GlcNAc that would meet the elements of the '245 patent.

The 1989 Sanford Article, however, did not disclose the elements of biocompatible p-GlcNAc as claimed in the asserted claims of the '245 patent. Instead, the Article was aspirational, suggesting possible uses for p-GlcNAc, without an actual invention of the biocompatible p-GlcNAc claimed in the '245 patent. Sanford testified that the term "biocompatible"

can mean many different things, which undermined HemCon's theory that the same biocompatibility claimed in the '245 patent was disclosed in the 1989 Sandford Article.

Although the article suggested p-GlcNAc with high purity and low variability, it did not disclose p-GlcNAc with no detectable biological reactivity as determined by biocompatibility tests. Marine Polymer presented evidence through its expert witness, Dr. Langer, that the "biocompatible" p-GlcNAc material disclosed in the 1989 Sandford Article, which was used in a dressing manufactured by 3M Corporation, caused bioreactivity.

Inherency is not established by possibilities or even probabilities. The missing elements must necessarily be present in the prior art. At most, HemCon provided evidence that the 1989 Sandford Article suggested the possibility of biocompatible p-GlcNAc that could have medical applications. Therefore, HemCon has not shown that the evidence at trial of anticipation by the 1989 Sandford Article is contrary to the jury's verdict.

HemCon provides little to show that evidence at trial proved that the '940 patent and the '373 patent disclosed biocompatible p-GlcNAc as claimed by the '245 patent. With reference to the '940 patent, HemCon states only that an elution test score of 0 "is an inherent property of the material." Def. Mem. dkt. 336-1, at 18. In the absence of evidence to support that theory,

HemCon's statement falls far short of the standard for judgment as a matter of law or for a new trial on anticipation. As Marine Polymer points out, Dr. Dornish and Dr. Langer both testified that the '940 patent did not disclose biocompatible p-GlcNAc.

In discussing the '373 patent, HemCon states that the "biocompatibility of the chitin and chitosan is made abundantly obvious by the teachings of Malette [the inventor of the '373 patent]." Id. at 19. HemCon explains that because the '373 patent discusses the use of chitin and chitosan material for hemostasis in open wounds, vascular grafts, heart valves, vascular patches, and other prostheses, the suggested uses "express that the [p-GlcNAc materials] of Malette are biocompatible." Id. The '373 patent does not disclose the specific biocompatibility elements claimed by the '245 patent, however.² Therefore, HemCon's argument does not show that the evidence at trial on anticipation by the '373 patent was insufficient to support the jury's verdict.

The jury concluded that HemCon did not show by clear and convincing evidence that the prior art references anticipated the

²In its reply, HemCon argues that because the '373 patent is presumed to be enabled and the claimed uses for the '373 patent would require testing, the '373 patent expressly discloses biocompatible p-GlcNAc. HemCon's enablement theory, first raised in its reply, is not persuasive.

'245 patent. Taking the evidence in the light most favorable to the jury's verdict, HemCon has not met its burden for purposes of its Rule 50(b) motion of showing no reasonable jury could have concluded that the asserted claims were not anticipated. In addition, HemCon has not convinced the court that the jury's verdict is against the weight of the evidence, for purposes of ordering a new trial.

B. Obviousness

Under 35 U.S.C. § 103, patent claims are invalid due to obviousness if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.'" KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 399 (2007) (quoting § 103). The determination of obviousness is a question of law, which is based on underlying factual findings. Ecolab, Inc. v. FMC Corp., 569 F.3d 1335, 1349 (Fed. Cir. 2009). The underlying factual issues include "the scope and content of the prior art, the differences between the prior art and the claims at issue, the level of ordinary skill in the pertinent art, and secondary considerations, otherwise known as objective indicia of nonobviousness." Id. (internal quotation marks omitted).

Invalidity due to obviousness must be proven by clear and convincing evidence. Verizon, 602 F.3d at 1338; Fresenius USA, Inc. v. Baxter Int'l, Inc., 582 F.3d 1288, 1294-95 (Fed. Cir. 2009).

HemCon contends that the jury's findings pertaining to obviousness in the verdict form demonstrate that the jury did not properly consider the evidence. HemCon also argues that the evidence at trial made a "strong and convincing case" that the asserted claims of the '245 patent were obvious.³ Marine Polymer objects, contending that the jury made no error and that the evidence did not show obviousness.

1. Verdict Form

The verdict form was submitted as a joint proposal by both parties. In subsection b of the obviousness section, the jury was asked about the differences between the prior art and the claimed invention.⁴ There, the jury was directed to indicate its

³As noted above, HemCon conflates anticipation and obviousness, making a review of its motion more difficult.

⁴A copy of subsection b of the verdict form is appended to this order.

findings on two charts, one for biocompatible poly- β -1 \rightarrow 4-N-acetylglucosamine and the other for biocompatible poly- β -1 \rightarrow 4-glucosamine.

Each chart was divided into three columns. The heading of the first column of the first chart was "Property of biocompatible poly- β -1 \rightarrow 4-N-acetylglucosamine," and the heading of the first column of the second chart was "Property of biocompatible poly- β -1 \rightarrow 4-glucosamine." The heading of the middle column in each chart was "YES Property IS in the Prior Art (For HemCon)," and the heading of the third column in each chart was "NO Property is NOT in the Prior Art (For Marine Polymer)." The jury was instructed to indicate its findings by checking the appropriate box "YES" or "NO".

The first column of each chart shows the headings "Property of biocompatible poly- β -1 \rightarrow 4-N-acetylglucosamine" and "Property of biocompatible poly- β -1 \rightarrow 4-glucosamine." The first listed property was poly- β -1 \rightarrow 4-N-acetylglucosamine in the first chart and poly- β -1 \rightarrow 4-glucosamine in the second chart. Following that are additional properties taken from the claim construction and the claims: "having low variability," "having high purity," "having no detectable biological reactivity as determined by biocompatibility tests," and properties relating to numbers of monosaccharides and molecular weights.

The jury checked the "NO" boxes next to all of the properties, including poly- β -1 \rightarrow 4-N-acetylglucosamine and poly- β -1 \rightarrow 4-glucosamine, indicating the jury's findings that no property of biocompatible poly- β -1 \rightarrow 4-N-acetylglucosamine or biocompatible poly- β -1 \rightarrow 4-glucosamine was disclosed in the prior art. HemCon asserts that the jury's "NO" responses to the properties, poly- β -1 \rightarrow 4-N-acetylglucosamine and poly- β -1 \rightarrow 4-glucosamine, were patently wrong, because poly- β -1 \rightarrow 4-N-acetylglucosamine and poly- β -1 \rightarrow 4-glucosamine were disclosed in the prior art.⁵ HemCon asserts that the jury's "NO" answers are wrong and support an inference that the jury did not properly consider the evidence, which HemCon contends supports a verdict in its favor.

Marine Polymer acknowledges that poly- β -1 \rightarrow 4-N-acetylglucosamine and poly- β -1 \rightarrow 4-glucosamine, also known as chitin and chitosan, were disclosed in the prior art and states that it never disputed that chitin and chitosan were disclosed in the prior art. Taken in the context of the evidence at trial and the verdict form itself, Marine Polymer contends, the jury was not asked to make an independent finding about poly- β -1 \rightarrow 4-N-

⁵In its reply, HemCon broadens its attack on the jury's verdict, arguing that the "NO" responses for properties with numbers and weight limitations were wrong because those properties were also disclosed in the prior art. The court will not consider issues first raised in the reply.

acetylglucosamine and poly- β -1 \rightarrow 4-glucosamine and instead the inquiry focused on p-GlcNAC having the properties of biocompatible poly- β -1 \rightarrow 4-N-acetylglucosamine and biocompatible poly- β -1 \rightarrow 4-glucosamine. Marine Polymer argues that when the charts in the verdict form are considered as a whole, the jury properly determined that biocompatible poly- β -1 \rightarrow 4-N-acetylglucosamine and biocompatible poly- β -1 \rightarrow 4-glucosamine were not disclosed in the prior art.

a. Meaning of Responses

Marine Polymer is correct that the entire focus of the invalidity phase of the trial was on biocompatible poly- β -1 \rightarrow 4-N-acetylglucosamine and biocompatible poly- β -1 \rightarrow 4-glucosamine and whether the biocompatible p-GlcNAC, as claimed in the '245 patent, was disclosed in the prior art. Indeed, it was not disputed that ordinary poly- β -1 \rightarrow 4-N-acetylglucosamine and poly- β -1 \rightarrow 4-glucosamine, chitin and chitosan, were found in the prior art. Viewed in the full context of the evidence and argument at trial, the headings of the columns shown in subsection b of the verdict form, and listed properties, the jury plainly understood that it was being asked whether biocompatible poly- β -1 \rightarrow 4-N-acetylglucosamine and biocompatible poly- β -1 \rightarrow 4-glucosamine were found in the prior art. In answering "NO" to each question, the

jury indicated its findings that neither biocompatible poly- β -1-4-N-acetylglucosamine nor biocompatible poly- β -1-4-glucosamine were found in the prior art.

Therefore, the jury's findings do not show an inattention to the evidence or a lack of reasoned decision-making, as HemCon argues.

b. Failure to Raise

In addition, HemCon failed previously to raise this issue at a time when the jury could have been asked to explain its findings, assuming the court determined that it was necessary to do so. To the extent HemCon argues now that the jury's findings are inconsistent, it was obligated to raise that issue before the jury was dismissed and having failed to do so, the issue is waived. See, e.g., Rodriguez-Garcia v. Municipality of Caguas, 495 F.3d 1, 9 (1st Cir. 2007) ("We have followed an 'iron-clad rule' that a party that fails to raise an objection based on verdict inconsistency before the jury is dismissed waives the issue.").

c. Obviousness Decided by the Court

Even if the jury's answers were viewed as wrong, as HemCon argues, despite the clear context of the trial and the verdict

form, any error would not be material to the outcome in this case. The jury did not render a verdict on obviousness, which is a legal issue for the court. Instead, the jury made factual findings pertaining to obviousness: the level of ordinary skill in the field, the differences between the prior art and the claimed invention, and objective considerations of nonobviousness or obviousness. The court, in a separate order, will make the legal determination as to whether the asserted claims of the '245 patent are invalid due to obviousness. In deciding the legal issue of obviousness, the court will consider the jury's factual findings in light of the evidence presented at trial and decide whether HemCon established, by clear and convincing evidence, that the elements of the asserted claims of the '245 patent were disclosed by the prior art.

Further, the court finds no basis to presume from the jury's findings, as HemCon urges, that the jury did not fulfill its obligation to consider the evidence and come to a reasoned decision.⁶ Evidence of invalidity was presented over the period

⁶In support, HemCon cites Lind v. Schenley Indus., Inc., 278 F.2d 79, 90-91 (3d Cir. 1960), where the court stated that complex cases might require careful scrutiny of the verdict but held that the subject matter in that case was simple and reversed the JMOL, requiring the trial court to reinstate the verdict. HemCon also cites Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc., 615 F. Supp. 2d 304, 310 (D. Del. 2009), which cited Lind for the principle that verdicts in

of four and a half consecutive days. Because the trial was bifurcated, the first phase was limited to the issue of patent invalidity. Three of the invalidity defenses, lack of written description, lack of enablement, and unpatentable subject matter, were dismissed at the close of HemCon's case. The only defenses submitted to the jury were anticipation and obviousness. As such, the invalidity phase of the trial was neither unusually long nor inordinately complex, and counsel did a good job of focusing on the issues that needed to be determined by the jury concerning those defenses.

The parties completed the evidence on Friday, April 23. The jury deliberated and returned its verdict on Monday, April 26. As observed during the trial, the jury was extremely attentive to all of the witnesses and evidence, appeared to take copious notes as permitted by the court, and remained focused throughout the trial.

Although the jury's deliberation period was relatively short, they were aided in the process by the immediacy of the evidence, by their trial notes, and by the evidence notebooks compiled by the parties and provided to each juror. Under the

complex cases may require careful scrutiny. Neither case addresses the issue HemCon raises about the verdict here, that a jury error should cause a presumption that the jury did not properly consider the evidence.

circumstances, the time taken to reach the verdict was not so short that it would compel an inference that the jury failed to deliberate. Even if it is assumed that HemCon's contention concerning the jury's findings is correct, any resulting error does not support a JMOL or a new trial. The court will make the obviousness determination, in a separate order, and in making that determination the court will have the opportunity to review the jury's findings.

2. Obviousness Findings

The jury found in Marine Polymer's favor on all of the obviousness factual findings. HemCon challenges the findings about the differences between the prior art and the claimed invention. As is discussed above, the jury found in Marine Polymer's favor on all of the properties of biocompatible p-GlcNAc, finding that none of the properties was disclosed in the prior art.

HemCon contends that the Sandford Article, the '940 patent, and the '373 patent disclosed all of the properties of the asserted claims of the '245 patent and that no reasonable jury could have arrived at contrary findings on the properties of biocompatible p-GlcNAc. Marine Polymer objects, pointing to evidence in the record which showed that the cited prior art did

not disclose biocompatible p-GlcNAc as claimed in the '245 patent.

As discussed above in the anticipation section, the evidence at trial supported the jury's findings that none of the cited prior art disclosed the properties of biocompatible p-GlcNAc. Although obviousness can be proven through a combination of prior art references, unlike anticipation, because none of the cited prior art disclosed the properties of biocompatible p-GlcNAc, as claimed by the '245 patent, the evidence at trial did not support findings for obviousness. Therefore, HemCon has not met its burden for JMOL or for a new trial on obviousness.

Conclusion

For the foregoing reasons, the defendant's motion for judgment as a matter of law and for a new trial (document no. 336) is denied.

SO ORDERED.


Joseph A. DiClerico, Jr.
United States District Judge

July 21, 2010

Attachment

cc: Julie M. Baher, Esquire
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